Remarks:

Reconsideration of the present application is respectfully requested. Claims 39 to 59 have been cancelled. Claims 60-72 have been added and are presently pending. Claims 60, 68, 69, and 71 are independent.

In the Office Action, claims 39 to 59 were rejected under 35 U.S.C. § 112, first and second paragraphs. Claims 39 to 59 have accordingly been cancelled.

New claims 60-72 have been added. These claims correspond to the claims of 39 to 49, and find support in the Examples of the present application.

Independent Claim 60 and Its Dependent Claims Conform to 35 U.S.C. § 112, First Paragraph

With respect to claim 60 and the dependent claims thereof, these claims comply with 35 U.S.C. § 112, first paragraph. This is because the specification describes preparing a recombinant plasmid using the DNA sequence of the 5' end of SEQ ID No. 3, to which ac is appended as described in paragraph bridging pages 16 and 17. The specification also describes inducing expression of the protein by transforming an *E. coli* bacteria with the recombinant plasmid as described in the second paragraph of page 17 and the second paragraph of page 21. The protein purification step is described in the third paragraph on page 17, and treating the purified protein with a restriction enzyme is described in both the second paragraph of page 18 and the second paragraph of page 21 to thereby obtain the HLA-F antigen. This HLA-F antigen is used to diagnose a tissue nonspecific cancer.

The obtained HLA-F antigen has a molecular weight of 31kD or 29kD as described in the second paragraph on page 18 and in the second paragraph on page 21, or of 25kD as described in the second paragraph of page 21, or of 18kD or 13kD as described in the second paragraph on page 18.

With any of these molecular weights, the HLA-F binds to the anti-HLA-F antibody as described in the first paragraph on page 20, the third paragraph on page 20 through the first paragraph on page 21, and the third paragraph on page 21. The HLA-F antigen with the molecular weight of 31kD is defined as the "HLA-F antigen which comprises at least an amino acid sequence corresponding to SEQ ID No. 6," as described in claim 60. This description is supported on the second paragraphs of pages 18 and 20. Therefore, claim 60 is fully and explicitly described in the specification. This demonstrates that the applicant was in possession of the claimed invention at the time of the application.

Independent Claim 60 and Its Dependent Claims Conform to 35 U.S.C. § 112, Second Paragraph

Additionally, independent claim 60 and its dependent claims also comply with 35 U.S.C. § 112, second paragraph, because the specification of the present application describes the blotting of the cancer cell-specific HLA-F antigen separated by SDS-PAGE on a Clearblot P membrane to prepare a filter for the detection of anti-HLA-F antibody in the third paragraph on page 18. In the fourth paragraph of page 18, the specification also describes submerging said filter for the detection of the anti-HLF-A antibody in sera which has been diluted in T-PBS. Accordingly, the specification fully and clearly supports "contacting a cancer cell specific HLA-F antigen, which comprises an amino acid sequence corresponding to SEQ ID No. 6, with a body fluid of a subject"

Additionally, the fourth paragraph on page 18 of the specification describes that the anti-HLA-F antibody is submerged in the subject's sera, where it is diluted and incubated for 90 minutes at 37°C for the reaction. This fully and explicitly describes that the anti-HLA-F antibody in a body fluid and the HLA-F antigen are bound to one another, which is described as an "immune complex" in the claims.

In the first paragraph on page 19, the specification describes that the filter for detection of anti-HLA-F antibody that has been submerged in the subject's sera for reaction is then submerged in the T-PBS containing alkaline-phosphatase labeled anti-human IgG rabbit antibody. Thus, the phrase "applying a secondary antibody to the immune complex in the body fluid, said secondary antibody being labeled" is fully supported. This same paragraph that the filter for detection of anti-HLA-F antibody that has been submerged in the subject's sera for reaction is then submerged in the T-PBS containing the labeled anti-human IgG rabbit antibody and incubated for 90 minutes at 37°C. This fully and clearly describes that "reacting the labeled secondary antibody with the immune complex in the body fluid." Additionally, in this same paragraph, the specification describes that the filter for detection of the anti-HLA-F antibody which is submerged in the T-PBS containing the secondary antibody is reacted with the alkaline phophatase reagent. Thereafter, as described in the second paragraph of page 19, color development of the filter for detection of the anti-HLA-F antibody is observed. This fully and clearly describes the claim language of "detecting the labeled secondary antibody reacted to the immune complex by using the label."

When the subject has a cancer, the subject must have an anti-HLA-F antibody in their body fluid. Therefore, if the subject's body fluid is applied to the HLA-F antigen, the anti-HLA-F antibody and the HLA-F antigen would necessarily yield the immune complex as recited in claim 60. Subsequently, the labeled secondary antibody is applied to the immune complex, thereby allowing the secondary antibody to bind to the immune complex. Then, the secondary antibody bound to the immune complex is detected by using the label to diagnose the subject as a cancer patient. Accordingly, the present invention actually links the outcome of detecting the immune response with the diagnosis of cancer, and so the subject matter is clearly and particularly claimed.

Independent Claim 68 Complies with 35 U.S.C. § 112

The new independent claim 68 complies with 35 U.S.C. § 112 because, as stated above, the specification of the present application describes that the obtained HLA-F antigen has a molecular weight of 31kD or 29kD as described in the second paragraph on page 18 and the second paragraph on page 20, or of 25 kD as described on the second paragraph on page 21, or of 18kD or 13kD as described in the second paragraph on page 18. Additionally, the specification teaches that the HLA-F antigen may bind to the anti-HLA-F antibody as described in the first paragraph on page 20, the third paragraph on page 20, and the second paragraph on page 21.

Among the above-mentioned HLA-F antigens, the antigen with the largest molecular weight of 31kD is "a HLA-F antigen...which comprises at least the amino acid sequence corresponding to SEQ ID No. 6." Additionally, HLA-F antigen having the molecular weight of 29kD, 25kD, 18kD, or 13kD is the HLA-F antigen comprising at least a part of the amino acid sequence of SEQ ID No. 6.

New claim 68 recites "contacting a cancer cell specific HLA-F antigen with a body fluid of a subject, said antigen having a molecular weight selected from the group consisting of 29kD, 25kD, 18 kD, or 13kD and which comprises at least a part of the amino acid sequence corresponding to SEQ ID No. 6," referring to the HLA-F antigen with a molecular weight of 29kD as described in the second paragraph on page 18 and the second paragraph on page 20; the HLA-F antigen with a molecular weight of 25kD as described in the first paragraph of page 21; and the HLA-F antigens with molecular weights of 18kD and 13kD as described in the second paragraph on page 18. Additionally, the remaining recitations of claim 68 correspond to those of new claim 60.

Accordingly, this claim is fully and clearly described in the specification.

Claims 69 and 70 Comply with 35 U.S.C. § 112

Independent claim 69 and claim 70, which depends therefrom, comply with 35 U.S.C. § 112 because, as shown in the Sequence Listing, SEQ ID No. 5 includes the same amino acid sequence as SEQ ID No. 6 from residue 23 to residue 237. Accordingly, the HLA-F antigen may bind to the anti-HLA-F antibody. Additionally, the remaining recitations of Claim 69 correspond to those of new Claim 60. Accordingly, this claim is fully and clearly described in the specification.

Claims 71 and 72 Comply with 35 U.S.C. § 112

Independent claim 71 and claim 72, which depends therefrom, comply with 35 U.S.C. § 112 because, as shown in the Sequence Listing, SEQ ID No. 4 is identical to the sequence between residue 44 and residue 258 in SEQ ID No. 6. Accordingly, the HLA-F antigen may bind to the anti-HLA-F antibody. Additionally, the remaining recitations of Claim 70 correspond to those of new Claim 60. Accordingly, this claim is fully and clearly described in the specification.

Conclusion

In view of the amendments and remarks herein, a Notice of Allowance appears to be in order and such is courteously solicited herein.

Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

Respectfully submitted,

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